

UNOCOM



WHITE PAPER

Scaling up the univocal identification
of medicines for patient safety,
better healthcare and public health

April 2024



TABLE OF CONTENTS



1	INTRODUCTION	3
1.1	Solving issues in healthcare and public health	3
1.2	The European Health Data Space	3
1.3	UNICOM is calling for action	4
1.4	Following sections	4
2	UNICOM ACHIEVEMENTS IN SUMMARY	4
2.1	Scaling up IDMP implementation	4
2.2	Sandbox, educational resources and implementation guides	5
2.3	Enhancing cross-border healthcare services	5
2.4	The new EMA electronic application forms and European Substance Database	6
3	ENSURING INTEROPERABILITY	7
3.1	Creating the foundation of an interoperable data ecosystem	7
3.2	Better use of medicinal product identification	8
4	TRANS-ATLANTIC COLLABORATION	9
5	SUSTAINABILITY AND WAY FORWARD	10
5.1	The EHDS and EEHRxF	10
5.2	Impact on healthcare systems	11
5.3	Outlook	11



ABBREVIATION COMPLETE FORM

eAF	electronic Application Form
eD	eDispensation
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
eHN	eHealth Network
EHR	Electronic Health Record
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
eP	ePrescription
EU-SRS	European Substance Registration System
FAIR	Findable, Accessible, Interoperable, Reusable
FDA	[United States] Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
GIDWG	Global IDMP Working Group
HL7	Health Level 7
HTA	Health Technology Assessment
IG	Implementation Guide
ISO IDMP	International Organization for Standardization [suite of standards for the] Identification of Medicinal Products
MAH	Marketing Authorisation Holder
MPD	Medicinal Product Dictionary
MPID	Medicinal Product Identifier
NCA	National Competent Authority
NCPeH	National Contact Point for eHealth
PCID	Medicinal Product Package Identifier
PhPID	Pharmaceutical Product Identifier
PLM	[EMA] Product Lifecycle Management Portal
PS	Patient Summary
ReEIF	Refined eHealth European Interoperability Framework
RMS	Referential Management Service
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SPOR	Substances, Products, Organisations and Referentials
SVG	Substance Validation Group
UMC	Uppsala Monitoring Centre

INTRODUCTION

The UNICOM project's main objective is to accelerate and scale up the **implementation of the suite of standards of the International Organization for Standardization for the Identification of Medicinal Products (ISO IDMP)** throughout the healthcare ecosystem.

The IDMP ensures that any medicine, and what it contains, can be accurately identified anywhere in Europe and indeed globally.

Unique identification is the foundation and the core of an interoperable and dynamic ecosystem (section 3) dedicated to better patient safety and better healthcare for all.

The ISO IDMP standards cover the **core identifiers** for a medicinal product, notably a common format for the **Medicinal Product Identifier (MPID)**, the **Medicinal Product Package Identifier (PCID)**, and for a global **Pharmaceutical Product Identifier (PhPID)**.



Figure 1: ISO IDMP, a suite of standards

UNICOM – facts

H2020 Funded Project

11.2020 – 05.2024 (54 months)

21M € Total Budget

90 Deliverables (135 incl. versions)

41 partners, 19 countries

- 9 Standard Development Organisations
- 11 National Competent Authorities for Medicinal Products
- 10 National eHealth Competence Centers / National eHealth Contact Points
- 4 Industry partners (Health IT)
- 2 Research Organisations
- 2 Medicinal Database Providers
- 3 Non-profit organisations

1.1 Solving issues in healthcare and public health

Many critical issues arising from the inaccurate identification of medicinal products can largely be solved through the use of the ISO IDMP standards suite, which helps to provide complete and accurate data about a medicinal product throughout its life cycle across the whole ecosystem. Example use cases are: **fighting drug falsification, avoiding negative drug-drug interactions** in medicine prescription and dispensing helping physicians and pharmacists make **substitution decisions** (if their first choice of product is not available), helping **prescribing decision support systems to perform drug-allergy, drug-condition checking** on any medicine the patient is taking or might newly take, irrespective of the European country from which the medication list was populated, as well as supporting the **reporting of adverse events (pharmacovigilance)**.

1.2 The European Health Data Space

UNICOM's work has been undertaken at an ideal point in the evolution of EU policy, which is well aligned to the wider use of IDMP standards. The future **European Health Data Space (EHDS) Regulation** will provide a legal framework which requires Member States to use standardised Electronic Health Record

(EHR) systems, electronic prescription and dispensation records which **conform to the European EHR Exchange Format (EEHRxF)** (section 5.1). The EHDS Regulation addresses use of data both within and across EU borders, recognising that data must be Findable, Accessible, Interoperable and Reuseable (FAIR).

With respect to the data identifying medicinal products, the IDMP standards go a long way towards making such data FAIR. The revision of the **Pharmaceuticals legislation**, will drive greater use of digital formats for submission of Marketing Authorisation dossiers, as well as will encourage the adoption of electronic patient information leaflets. Adverse event reporting tools have since long required the use of standardised medicinal product identification data, and indeed **EMA EU IDMP Implementation Guide (EU IG)** requires the use of ISO IDMP compliant data when new submissions for Marketing Authorisation are made.

1.3 UNICOM is calling for action

Meeting the market authorisation requirements and leveraging the power of standardised identification of medicines require significant change along the full length of the pharmaceuticals value chain. The UNICOM project has assessed and addressed many of the changes that will be needed and has provided tools and baseline analyses to do so. However, significant action is needed from all stakeholders in the medicinal products value chain. **UNICOM calls upon all stakeholders, and in particular on state actors to come together to address the key challenges** related to interoperability and international co-operation, and focus specifically on:

1. Creating an interoperable and increasingly integrated medicinal product data ecosystem
2. Leveraging the power of the Pharmaceutical Product Identifier in the international context
3. Using ISO IDMP standards implementation as a key enabler of the European Health Data Space.

1.4 Following sections

In the next sections, UNICOM achievements are described in more detail (section 2), followed by an in-depth exploration of interoperability issues at stake (section 3). Global – including transatlantic – collaboration is then covered (section 4). We then look at the way forward, with a focus on the future European Health Data Space (EHDS) (section 5). Calls-to-action are made in the appropriate sections.

2 UNICOM ACHIEVEMENTS IN SUMMARY

The UNICOM partners have opened and developed the conversation between key stakeholders on medicinal product identification. They have worked together to break down silos between the actors in the medicinal product value chain to build a strong consensus: **medicinal product data interoperability and governance is a shared responsibility**.

2.1 Scaling up IDMP implementation

UNICOM partners have worked together on **transitioning to ISO IDMP implementation**. They have collaborated with the **European Directorate for the Quality of Medicines & HealthCare (EDQM)** on the latest standard for dose forms, and with **World Health Organization's Uppsala Monitoring Centre (UMC)** on its systematic methodology for PhPID generation. Impact of the choice of specific terminologies for use

cases extensions has been documented. Approaches to support National Competent Authorities (NCAs) in their legacy conversion work have been proposed.

A PhPID uniquely identifies a pharmaceutical product by its substance, dose form and strength and may reside in in each country's medicinal product dictionary. A global PhPID can be calculated by the UMC. The PhPID itself is not one of the Project deliverables but UNICOM's understanding is that PhPID is automatically generated making use of building blocks, such as substances. Two aspects that are relevant here are data cleansing as well as patterns for generating PhPIDs. It was observed by partners that PhPID is still not part of the EMA EU IG of ISO IDMP implementation in the EU. However, within the consortium NCA network, there has been significant progress on the usage of structured data elements based on EMA Substances, Products, Organisations and Referentials (SPOR) terminology.

2.2 Sandbox, educational resources and implementation guides

UNICOM partners have produced **databases of sample products in IDMP format** from which partners have been able to learn. UNICOM has implemented **a server (UNICOM IDMP server) to store and evaluate IDMP conformant product datasets**, which provides a “sandbox” for pilots.

UNICOM partners have also developed **educational resources for the developers of Electronic Health Record (EHR) and pharmacy systems**, to help them adapt to the use of ISO IDMP standards. The needs of healthcare professionals and patients have been addressed through the development of a patient facing app that offers ISO IDMP-enabled function related to their medication. They will have a particular application when a patient travels to another country in which a physician or pharmacist needs to substitute a product that is not available in the visited country.

UNICOM has not developed new interoperability assets but has worked closely with HL7 as it has developed a FHIR specification for IDMP conformant medicinal products. This UNICOM Interoperability Guide is published by HL7 in open access. UNICOM partners contributed to the implementation guidelines based on FHIR Release 5 (FHIR R5) published on the EMA website. A transatlantic **Community of Expertise** with participants from across the globe has emerged. It has been engaged in all progress made during the project lifetime. Consequently, the EU/EEA is now considered as the **world laboratory for ISO IDMP implementation**.

2.3 Enhancing cross-border healthcare services

UNICOM partners actively foster **a close collaboration with the eHealth Network (eHN) and MyHealth@EU** communities to drive the adoption of ISO IDMP within the services already in routine operations, which allow ePrescriptions (eP) / eDispensations (eD) and Patient Summaries (PS) to be exchanged in a secure and interoperable way among the participating countries in the EU. The close collaboration yielded significant results, such as the improvement of **eHN guidelines for PS and eP/eD services, incorporating recommendations for the adoption of ISO IDMP and EMA SPOR data models and code systems**.

Additionally, two change proposals were co-created with these key stakeholders and successfully accepted by Member States. These change proposals have paved the way for the future incorporation of IDMP identifiers. They also promoted improvements in describing medicines, encompassing aspects such as complex packaging, diverse representations of dose forms and strengths, and the identification of prescribed and dispensed medicinal products through distinct identifiers.

Due to the unavailability of IDMP identifiers, MyHealth@EU is not yet promoting the full implementation of ISO IDMP, it aims to utilise the ISO IDMP data model and EMA SPOR value sets to enhance the services and enable Member States to submit their data in a simplified yet standardised format. It is pertinent to acknowledge that even if a Member State cannot provide those data, they can still access the services, with the additional attributes and layers of information remaining optional for each respective country.

2.4 The new EMA electronic application forms and European Substance Database

Together with the **European medicines regulatory network (EMRN)**, a **new tool for creating ISO IDMP compliant application forms** has been developed and a first release was launched for variations of centralised products. With this tool, IDMP compliant data will be available right from the start of the registration process.

A **scientific substance database, the European Substance Registration System (EU-SRS)** with ISO-IDMP compliant structured substance data was established to ensure unique and harmonised coding of substances. This high-quality substance database including their molecular structure allows its use in Big Data approaches. The data were harmonised with FDA Substance data (e.g., Chemicals) in the Global Substance Registration System (G-SRS) taking European legislation into account. The substance database was finalised by UNICOM together with the EMRN and has been handed over to EMA for hosting and maintenance of the system; the maintenance of the substances data in EU-SRS is the responsibility of the Substance Validation Group (SVG) of the Heads of Medicines Agencies (HMA). UNICOM members in particular have **increased data quality based on the integration of SPOR terms**. This in particular relates to Substance, Organisations, and Referentials.

The 11 participating NCAs have made significant progress in IDMP implementation in their national systems either by refactoring or building completely new IDMP compliant national databases. The NCAs continuously shared best practises, experiences and knowledge which is documented, and made publicly available on the UNICOM website. This material can be used as **training material for continued ISO IDMP implementation in EU/EEA NCAs** and is open for use by other relevant stakeholders.

An overview of selected achievements is presented in the following figure. For further information, please refer to the UNICOM website, in particular under Resources.

Impact on Processes

- Gap Analysis of Existing and Need for New Standards and Profiles
- EU-SRS Implementation and going live
- DADI – Electronic application forms
- IDMP implementation on National level
- Contributions in eHDSI Waves 6 and 7 (2022-2024)
- IDMP Coding Principles and Guidance for ICSRs
- Implementation guidelines for use of IDMP within MPD

Resources and Assets

- IDMP in a capsule
- Minimum Attribute List and Pilot Product List (PPL)
- UNICOM FHIR IDMP server, UNICOM FHIR IG, and IDMP product browser for test and reuse
- Smart Substitution Component and Patient Facing App

Knowledge exchange

- Community of Expertise
- Trans-Atlantic exchange and workshops
- NCA Best Practice exchanges
- Contribution to Research papers

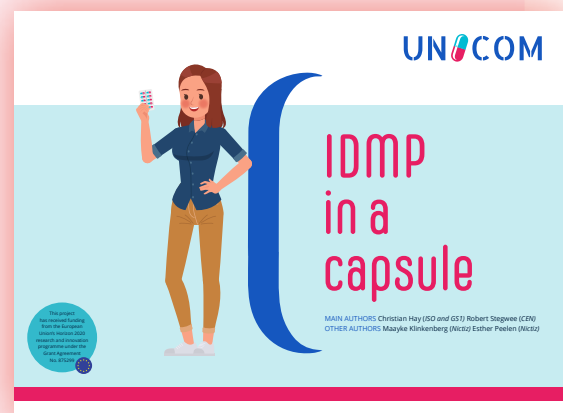


Figure 2: Overview of selected UNICOM achievements

3

ENSURING INTEROPERABILITY

Interoperability is best defined as “the ability of different information systems, devices, and applications (systems) to access, exchange, integrate, and cooperatively use data in a coordinated manner, within and across organisational, regional, and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally”. **Technical and semantic interoperability** is usually the central focus when discussing interoperability, but it is important also to consider the different layers to create a truly interoperable ecosystem: legal/regulatory, policy, care process, information, applications, and infrastructure need all to be considered as described in **Refined eHealth European Interoperability Framework (ReEIF)**¹.

3.1 Creating the foundation of an interoperable data ecosystem

UNICOM envisions **interoperability across the value chain** with the use of **trusted high-quality data**. To make use of the data within the eHealth sector, both locally and on a European level, collaboration between NCAs and eHealth organisations is getting increasingly important.

The principle of interoperability states that **data is created with the objective in mind that it needs to be used by other systems downstream**; this implies that data needs to conform to standards that are influenced also by users that do not play a role at the source of the data.

Medicinal product data in the broad sense, as required for the safe use of medication, does not originate at the point of care, in an EHR system. The origin of medicinal product data comes from the marketing authorisation holders of medicinal products. Therefore, UNICOM has focused on e.g. ISO IDMP compliant standards for the **electronic application forms (eAF)** for submission of applications for both new medicinal products and variations of medicinal products. The move towards requiring ISO IDMP compliance in all new regulatory submissions for Marketing Authorisation is a huge step towards building a reliable medicinal product data.

EHR systems have not been designed with the objective of cross-border or secondary use of the data. They are serving, and should be serving, the needs of the delivery of healthcare to patients by (teams of) healthcare professionals within a healthcare provider organisation. Solving the problem of **interoperability of medicinal products data at the source** is essential for EHDS to work as a federated system with “downstream” use of medication data and also personal health data.

With the principle of interoperability across the value chain, it is recognised that the source of data elements within one data set may well be spread across many different organisations, that are part of the value chain. The full IDMP landscape illustrated by UNICOM partners identifies the value chain for medicinal products with a direct impact for all organisations involved in the medicinal product lifecycle.

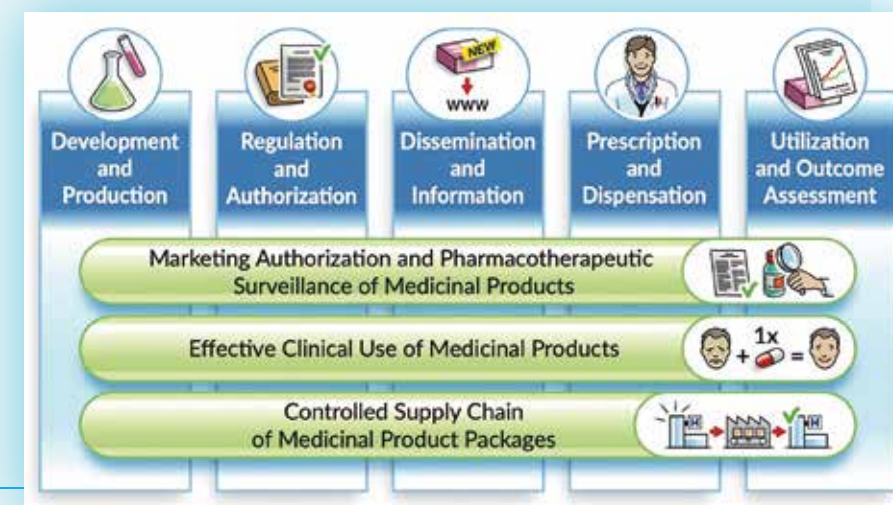


Figure 3: The Medicinal Product Data Value Chain according to UNICOM

¹https://health.ec.europa.eu/document/download/7cc56460-46ea-4fd7-9064-ac1a14a2a14e_en

This structured data, as embedded in the systems of the pharmaceutical industry, will be used to populate databases for the European medicines regulatory network (EMRN) through the eAF and, after rigorous quality control by the NCAs, will make its way into the national **medicinal product dictionaries (MPDs)**. These data will then be used by health care professionals to prescribe medication to their patients and to consult the product information to check for contra-indications, interactions, and other relevant data to ensure safe use of this particular medication. Should an adverse drug reaction occur, the patient or the clinician needs to communicate back in such a way that the authorities and industry can take appropriate action (pharmacovigilance) ensuring thus a complete integrated loop.

Data quality and consistency are essential prerequisites for effective and efficient data sharing. In UNICOM's view, **the trusted source of quality medicinal product data are the NCA**, even though data comes from the MAH (Marketing Authorisation Holder). Hence, the national contact points for eHealth (NCPeH) should base their work on the transformation of local medication information into the "pivot document" to be shared in the cross-border MyHealth@EU infrastructure. This transformation is based on trusted and interoperable data provided by the NCAs and EMA; this will guarantee that data can be trusted and that the infrastructure which makes the data available is maintained. Wide and consistent ISO IDMP implementation is a key enabler for the upcoming EHDS, allowing all actors to use trusted and harmonised data on medicinal products, which will in turn contribute to patient safety.

A key condition for enabling and maintaining **interoperability of the value chain** is the creation of an interoperable **data ecosystem and its multi-stakeholder governance**. IDMP offers Member States a unique opportunity to further develop the value chain and better integrate the different actors using medicinal product data.

CALL TO ACTION :

- UNICOM calls upon EU Member States to prioritise the implementation of ISO IDMP standards in all new initiatives undertaken to roll out national components of the future EHDS.
- UNICOM calls upon the European Commission to support a seamless flow of medicinal product data across the whole landscape, i.e. regulators, pharmaceutical industry, medicinal product dictionaries (MPDs), health and care organisations, digital health organisations, technology developers and providers, researchers, public health, Health Technology Assessment (HTA) bodies, patients/citizens.

3.2 Better use of medicinal product identification

In most countries, information about medicinal products with a marketing authorisation is published by the NCA in a public registry. If or how this data is used by the eHealth applications (for example, for ePrescription) varies a lot across different countries. It is important therefore to report and demonstrate **the efficiency gains from reusing consistent data between European and national systems**.

The benefit of using ISO IDMP at national level, i.e., the value of using standardised identification, is demonstrated in cases where different medicinal product identifiers are used in regulatory processes for distribution and reimbursement. Many countries using multiple identifiers often exploit a virtual product layer on top of product identifiers. In these cases, ISO IDMP offers an important opportunity to both creating a national ecosystem and making it interoperable with other EU countries.

Mapping between terminologies is needed and SPOR RMS can be used as a source for retrieving mapping information. In UNICOM, a mapping from EDQM to SNOMED CT dose forms has been performed. Moreover, both EDQM and SNOMED CT dose form descriptions are based on the same ISO standard, and hence very similar. It is thus essential to reuse and maintain existing mapping information (SPOR RMS) to avoid additional effort.

CALL TO ACTION :

- UNICOM calls upon all NCAs and EMA to continue the mapping of national terms to SPOR master data to ensure that necessary data can be consistently shared.
- UNICOM calls upon Member States regulators and other stakeholders to engage actively and collaboratively in utilising ISO IDMP implementation beyond the immediate need of cross-border related use cases.

4

TRANS-ATLANTIC COLLABORATION

ISO IDMP is a set of international standards which the **United States Federal Drug Administration (FDA)** is also implementing. It is however important to highlight that IDMP is a data model and does not include terminologies, which means that EU and US data will not automatically become interoperable after implementing ISO IDMP. However, it does demand creating similar concepts for medicinal products, which means that identification and comparison of products becomes a lot easier. **The Pharmaceutical product Identifier (PhPID)** has the potential to associate medicinal products of similar composition in different countries using the same terminology by representing information **about substance, dose form and strength at different levels of precision or aggregation**. It is therefore a very powerful concept to ensure global alignment.

UNICOM has supported the discussions around the PhPID role and impact with all actors of the value chain and organised several working sessions bringing together key stakeholders on both sides of the Atlantic. Several world-wide pilots were conducted under the supervision of WHO-UMC, focusing e.g., on challenges regarding dose form and mapping to regional terminologies; identifying several issues for unique identification of substance and expression of strength. This resulted in **proposed actions for updates of the ISO IDMP standards** and continued work on best practices and business rules.

UNICOM has been in contact with the **Global IDMP Working Group (GIDWG)** created in October 2021. GIDWG started as a collaboration between FDA, WHO-UMC, and EMA, but is gradually expanding its scope of stakeholders. GIDWG has since then been working on five additional projects to support the PhPID production: Global Substance ID, Global Dose Form Identifier, Strength Definition Identifier, HL7 FHIR for IDMP and a Global PhPID Operating model.

The operational model for both query and assignment of global PhPIDs, through a service provided by WHO-UMC, has been successfully tested during a series of HL7 FHIR Connectathons, supported by the UNICOM project. Several actors active within UNICOM believe that the recognition of WHO-UMC as the official lead in the creation and maintenance of the global WHO-UMC PhPIDs, as well as Global WHO-UMC Substance IDs, could be a key milestone to progress towards global alignment.

The creation of a repository of global identifiers for national medicinal products (PhPIDs) by WHO-UMC provides a sandbox to take appropriate decisions on PhPID management. The ISO IDMP pharmaceutical product identifier (PhPID) business rules are defined in the standards. The used terminologies for data input differs across regions and the anticipated use cases.

Actual operational use of these PhPID services, whether European² or global, or in regulatory and clinical practice, depends on the incorporation of specific current medicinal product data in the new ISO IDMP

2- It was observed by UNICOM partners that PhPID is still not part of the EMA EU IG of ISO-IDMP implementation in EU. Some UNICOM partners do not see a clear business case for the use of PhPID in Europe. However, there has been significant progress on the usage of structured data elements

Unique Product Identifiers

PHPID	Pharmaceutical Product ID
MPID	Medicinal Product ID
SID	Substance ID
PCID	Medicinal Product Package ID
DCID	Data Carrier ID (GTIN)

Figure 4: Five IDMP-compliant Unique Product Identifiers

compliant infrastructure. This is a major task, sometimes described as “pharmaco-archaeology”, because it cannot be taken for granted that all relevant data (e.g. substances and dose forms in standardised coding systems) are easily available for products that have been on the market for a long time.

The finalisation of the EU SRS substance database achieved in the UNICOM project built a foundation for further world wide alignment. A sample (4 substances) of the central databases managed by several Member States has been assessed against a set of ISO IDMP related criteria. The learnings from this exercise have provided a new training ground and paved the way towards the development of appropriate tools which **will support Member States in dealing with their existing data**. The dose forms ontology developed by UNICOM can, for example, be used to map all local dose forms to the high and intermediate level of the dose form ontology, bringing an important contribution to legacy Conversion.

CALL TO ACTION :

- UNICOM calls on its international partners to leverage the tools developed by UNICOM and to consolidate sample data originating from EU and non-EU countries in an open public database in order to offer National MPD providers new opportunities for testing and piloting.
- UNICOM calls upon its international partners to continue to enlarge the support for the exploitation of the PhPID, developing reference implementations for using PhPIDs in clinical decision support and other clinical use cases.

5 SUSTAINABILITY AND WAY FORWARD

5.1 The EHDS and EEHRxF

UNICOM has established tight links with the eHealth Network working groups to support cross-border prescription leading to more mature ISO IDMP compatible specifications and solutions to previously identified problems. This is critical in the context of the roll out of the future European Health Data Space (EHDS) for which a wide and consistent implementation of ISO IDMP is key in allowing all those using the EHDS to use trusted and harmonised data on medicinal products.

The European EHRxF, to which the EHDS Regulation makes direct reference, already includes direct references to IDMP and its implementation in Europe. These are present in both Patient Summary and ePrescription/ eDispensation specifications of MyHealth@EU and will be included in the hospital discharge report. However, if the actual data is not available, as it is usually the case today, this remains largely virtual because the required connection between national authoritative data across Member States is not implemented.

It is crucial to the success of the future EHDS therefore that the linkage of the national product data with the IDMP/SPOR data is maintained by the NCAs and EMA, and that those references are included in the MyHealth@EU specifications. Every mapping of national product data into the Master Value Set Catalogue for medication data should thus be generated based on trusted NCA data.

It is essential to support initiatives which will demonstrate the implementation of IDMP across the whole value chain. IDMP tremendous opportunities cannot be exploited by lack of trusted medicinal product data that is compliant with IDMP. UNICOM has made great progress to address this issue, providing implementation guidelines and documenting best practices. European projects starting now could use those assets.

CALL TO ACTION :

- UNICOM calls upon the European Commission to ensure that the EEHRxF is IDMP-ready and contributes to the implementation of the European Health Data Space (both for primary and secondary use of health data) by establishing interoperable high quality European master data on medicinal products, supporting the reuse of existing data services (e.g., SPOR, to enable use of IDMP-compatible data).

5.2 Impact on healthcare systems

It is vital that ISO IDMP is adopted and well penetrated across the healthcare system. Electronic Health Record systems need to be able to access IDMP-enabled medicinal product databases that enable a treating clinician to look up the identity of an unfamiliar bottle or packet of medicines, brought in by a visiting patient, perhaps by scanning its QR code, discover what the product is and also the product that is the closest match to it if the original item is not available in their country. Ideally this should be electronically integrated in the EHR so any new prescription they are about to give can be checked for drug-drug interactions with the medicines the patient is already taking. The clinician can also be guided towards a safe substitution if a new prescription of an existing product is also needed.

Patients need to experience similar confidence about medicines compatibility if they need to purchase an over-the-counter medicine whilst travelling, knowing it can be computer checked against interactions with their existing medicines, irrespective of their country of origin and irrespective of the country in which they are now trying to purchase a new product.

This adoption of IDMP will improve patient safety and reduce healthcare costs from accidentally inappropriate prescribing and the taking of medicines by patients that are unsuitable given their existing medicines, from whichever country.

Governance of the utilisation of the ISO IDMP standards within the European health systems needs to be undertaken actively at Member State and EU level, in order that the global perspective to guarantee maximum added value can be achieved in due course. Decisions should be taken based on collected knowledge and documenting possible scenarios.

An ambitious integrated workplan considering the whole value chain with clear operational objectives and deadlines needs to be drafted and discussed. Sustainability will be greatly supported by the EMA EU IG and further development of the secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the EU, the EMA Product Lifecycle Management Portal (EMA PLM) should be supported as high priority.

UNICOM calls upon the EU and Member States to sustain the implementation of ISO IDMP in EU healthcare systems by:

CALL TO ACTION :

- UNICOM calls upon the EU and Member States to urgently consider the use of European structural funds and/or other financial channels to support Member States accelerating their IDMP transformation journey. Further support initiatives to develop the new skills and knowledge needed for the transition. Propose a continuous monitoring process with sharing of best practice examples and twinnings to measure progress towards IDMP compliance.
- UNICOM calls all major European real world data networks to consider linkage with IDMP identifiers.
- UNICOM calls upon the European Commission to leverage the opportunity of upcoming legislations to continuously support ISO IDMP implementation.

5.3 Outlook

UNICOM is a strategic project which has delivered exceptional results with significant immediate impact and outcomes with potential long-term impact. It has successfully brought together stakeholders from all relevant sectors of the European medicinal product ecosystem to drive the harmonised identification of medicines throughout Europe.

National Competent Authorities play a central role in achieving a univocal drug identification system, essential for secure cross-border data exchange and the delivery of cross-border Patient Summary, ePrescription and eDispensation services. UNICOM's potential impact is substantial, as it has accelerated the capability of NCAs for health data exchange within the European Union while also contributing to additional domains including clinical research and pharmacovigilance.

To facilitate the necessary data provision, all NCAs must implement IDMP standards, including robust linkages to the European Medicines Agency's master data management for Substances, Products, Organizations, and Referential (SPOR). Ensuring effective collaboration and shared responsibilities among NCAs, EMA, national eHealth agencies and other relevant authorities is pivotal, bearing direct implications for policy formulation and proactive engagement of public authorities across Europe.

IDMP must urgently also be adopted, for all medicinal products in current use, across all of the data flows between manufacturers, regulators, HTA, MPD developers, EHR system developers, accompanied by relevant training to healthcare professionals including prescribers and dispensers. Clinical research also requires the precise specification of medicinal products within health data, especially to advance personalised and precision medicine. IDMP must therefore also be integrated within clinical research platforms and their common data models.

Based on the excellent outcomes of UNICOM, a follow-up initiative is uniquely positioned to drive further deployment and scale up and address areas for improvement, including this urgently needed penetration across the whole of healthcare. There is a need to further strengthen collaboration with the European Medicines Agency, fostering a more cohesive partnership to advance shared objectives of scaling up IDMP standards deployment to a) to enhance digitalisation in the medicinal product lifecycle, and b) contributing to patient safety, improving efficiency, and boosting innovation.





With the support of





Project acronym: UNICOM

Project full title: Up scaling the global univocal identification of medicines in the context of Digital Single Market strategy

Call identifier: H2020-SC1-DTH-2019

Coordinator: empirica Gesellschaft für Kommunikations- und Technologieforschung mbH

Acknowledgement

The UNICOM project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299.

Disclaimer

This document reflects only the views of the authors and not necessarily all the affiliated organisations. The European Commission is not liable for any use that may be made of its contents. The information in this document is provided "as is", without warranty of any kind, and accept no liability for loss or damage suffered by any person using this information.

© 2019-2023. The participants of the UNICOM project.